K082137

DLMS 14201 N. 87th Street, Suite A-105 Scottsdale, AZ 85260

Section G

FEB 10 2009

510(k) Summary

510(k) Summary	This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92
Applicant	Dental Laboratory Milling Supplies (DLMS) 14201 N. 87th Street, Suite A-105 Scottsdale, AZ 85260
Contact Person	Name and Title: Scott Atkin, Founder DLMS Ph: 480-948-0466 Fax: 480-443-7666
Date Prepared	25 JUL 2008
Trade Name	DLMS-Zirblocks
Classification Name	Porcelain Powder for Clinical Use
Common Name	CAM-Blanks
Predicate Devices	Legally marketed device to which we claim equivalence: Metoxit CAM-Blanks, Metoxit AG, K072569
Description	DLMS-Zirblocks is a partially sintered yttria (yttrium oxide) stabilized zirconia (zirconium oxide) powder that is capable of machining by modern methods. The material is designated as TZP (slightly stronger) or TZPA (slightly more translucent). The dentist prepares the tooth surfaces, sends a properly prepared impression of those surfaces to the dental laboratory where it is scanned and an inlay or onlay prepared by modern computerized lathe methods, sintered to full density, and returned to the dentist. The dentist then finally prepares the tooth surfaces involved and cements (lutes) the inlay or only in place with standard dental adhesives (luting) materials. The material is radio-opaque, for ready visualization.
Indications for Use	Intended for use in CAD/CAM technology to produce copings, bridges, and framework core material usage for fixed prosthodontics. Then veneered with porcelain glass to create final restoration.
Technological Characteristics	The technological characteristics between the predicate devices and the proposed device are identical. There is no difference in fundamental technology. They have the same intended use and are made from the same materials.
Substantial Equivalence	The product is the exact same material used for the predicate device, the Metoxit CAM-Blanks, and is equivalent in function and intended use to the predicate device.
Conclusion	There are no significant differences between the DLMS-Zirblocks and the predicate device, the Metoxit CAM-Blanks, and therefore, the DLMS-Zirblocks are equally safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dental Laboratory Milling Supplies
Mr. Scott Atkin
14201 North 87th Street
Suite A-105
Scottsdale, Arizona 85260

FEB 10 2009

Re: K082137
Trade/Device Name: DLMS-Zirblocks
Regulation Number: 872.6660
Regulation Name: Porcelain Powder For Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: February 4, 2009
Received: February 5, 2009

Dear Mr. Atkin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082137

Device Name: DLMS-Zirblocks

Indications for Use:

Intended for use in CAD/CAM technology to produce copings, bridges, and framework core material usage for fixed prosthodontics. Then veneered with porcelain glass to create final restoration.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sonya Purvis

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082137